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(54) **Implant for suspension of the urinary bladder in cases of incontinence of urine in women**

Implantat zum Aufhängen der Harnblase bei Inkontinenz von Frauen

Implant pour suspension de la vessie dans les cas d'incontinence urinaire chez la femme

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Description

[0001] The invention relates to an implant for suspension of the urinary bladder in cases of incontinence of urine in women.

[0002] Treatment of incontinence of urine in women is distinguished by a large number of different treatment concepts. While milder forms of stress incontinence can still be treated successfully by training of the pelvic floor and pharmacological treatment, only surgical treatment remains for severe forms of incontinence of urine. The aims of surgical treatment are to achieve anatomically adequate and permanent displacement of the neck of the bladder cranio-ventrally in the abdominal pressure region, and in the event of descensus genitalis and prolapse to take reconstructive measures to render the insufficient suspension and support apparatus capable of carrying the load again.

[0003] About 200 operating methods, modifications and modified modifications demonstrate the disagreement in the therapeutic procedure. In view of the multifactorial development of stress incontinence, the surgeon as a rule chooses the method which most closely meets the requirements existing in the individual case. Transvaginal and suprapubic accesses are combined, as are gathering of tissue, fixations and suspending bridles of fascial ribbon, lyodura or alloplastic material. The individually different constellations of findings do not allow a general preference to be given to a particular operating method. Rather, it is a matter of carefully choosing, considering and deciding from the entire range of therapeutic possibilities available.

[0004] An implant is known from EP-A-0639355 for variably control the aperture of the urethra in cases of incontinence of urine in women by a controlled injecting of fluid in an expandable chamber being placed below the urethra, wherein two first projections and two second projections start from said chamber.

[0005] The object of the invention is to provide an implant for reliable treatment of incontinence of urine in women, especially in cases of extreme weakness of the pelvic floor with prolapsing anatomical displacement of the organs of the lesser pelvis, and in patients following several unsuccessful previous operations using the usual techniques.

[0006] This object is achieved by an implant for suspension of the urinary bladder in cases of incontinence of urine in women, having the features of Claim 1. Advantageous embodiments result from the sub-claims.

[0007] After the implant according to the invention has been inserted in a surgical operation, as described below, the urinary bladder lies with a wide surface area on the implant, which means that an absolutely stable bilateral fixation of the urinary bladder is achieved both in the bladder neck region and in the region of the apex of the bladder. By hanging at four points by means of the two first projections and the two second projections starting from the base of the basic structure of the im-

plant, the urinary bladder is supported elastically as on a hammock as a result of the implant, regardless of the condition of the pelvic floor. Renewed prolapse or descensus even under load can thus reliably be avoided.

5 With the implant according to the invention, not only the bladder outlet but the entire urinary bladder is incorporated in a broad stable support which supports the entire base of the bladder. This results in no increase in discharge resistance, but exclusively stress-proof relieving of the sphincter vesicae externus. There is no risk of obstruction if the implant is incorporated correctly.

10 [0008] In a preferred embodiment, the basic structure of the implant has several layers. In this, a net of polypropylene, which is not absorbable, can be provided with a porous coating of an absorbable composite material of polyglactin 910 (a copolymer of glycolide and lactide in a ratio of 9:1) and polydioxanone on both sides.

15 [0009] In the course of breakdown of the absorbable contents of the implant in the body, replacement of these contents by connective tissue with construction through the net, which remains permanently, takes place. The net is therefore secured from dislocation and the surrounding tissue is protected from mechanical irritation or erosion. A stable, permanent suspension of the bladder results.

20 [0010] The invention is described in more detail below with the aid of an embodiment example. The drawing shows in

30 Figure 1: a plan view of an embodiment of the implant.

[0011] Figure 1 shows a plan view of an embodiment of an implant according to the invention. The implant comprises a flat, flexible basic structure.

35 [0012] A base 1 is triangle-like to elongated oval in shape and has a longitudinal axis L-L. In the embodiment example, the base 1 rather resembles a triangle with the corners 2, 3 and 4, the corner 2 (through which the longitudinal axis L-L of the base 1 runs) being rounded. The area of the base is about 30-50 cm².

40 [0013] From the base 1, close to the corner 2 but at a distance from this, a first projection 5 which is bridle-like in construction starts. The first projection 5 runs on the left-hand side of the longitudinal axis L-L at a sharp angle with respect to the longitudinal axis L-L, which is less than 20° in the embodiment example. Another first projection 6 which has the same form as the first projection 5 is arranged in mirror symmetry to the longitudinal axis L-L.

45 [0014] From the corner 3 of the base 1, a second projection 7 which runs on the left-hand side of the longitudinal axis L-L and essentially parallel to this starts. The second projection 7 is thus generally directed in the opposite direction to the first projection 5, i.e. while the first projection 5 in Figure 1 extends (at an angle) upwards, the second projection 7 runs downwards. Like the first projection 5, the second projection 7 could also form an angle to the longitudinal axis L-L of the base 1 which differs from 0°. From the corner 4 of the base 1, another

second projection 8 which runs in mirror image to the second projection 7 in respect of the longitudinal axis L-L starts. The two second projections 7 and 8 have the same dimensions and are longer than the two first projections 5 and 6.

[0015] Between the two first projections 5 and 6, in the region of the corner 2, the base forms a semicircular or oval extension about 2-3 cm² in area. The purpose of this extension is suspension of the bladder neck and of the proximal urethra, so that after the implant has been inserted, complete support of the base of the bladder, bladder neck and proximal urethra is achieved overall.

[0016] Holes 9 which can be of assistance during insertion and fixing (suturing in place) of the implant can be provided close to the ends of the first projections 5 and 6 and of the second projections 7 and 8.

[0017] In the embodiment example, the implant has three layers. The middle layer comprises a non-absorbable, flexible net of 0.7 mm thickness made from monofilament polypropylene threads. This material does not lose its physical properties in the body in the long-term, and is insensitive to variations in pH. It is elastic and unidirectionally extendable, to allow changes in shape, such as exist, for example, during pressure on the abdomen, due to the filling level of the bladder or during micturition.

[0018] A porous coating of an absorbable composite material comprising polyglactin 910 and polydioxanone is applied to both sides of the polypropylene net. In the embodiment example, these outer layers are absorbed without residue within about 120 days after implantation.

[0019] The basic idea of this material combination is to combine the connective tissue-conductive properties of the layers of the composite material, which are preferably constructed as nonwoven layers (fleece), with the permanent stability of the polypropylene net. Findings from animals experiments show that a large quantity of fibrohistiocytic tissue is constructed through the nonwoven layer on the surface within the first three weeks. In particular, filaments of polyglactin 910 serve as conductors for the formation of aligned collagenic connective tissue fibres which, in contrast to scar tissue, show no tendency to shrink at all. As absorption of the outer layers progresses, loose collagenic connective tissue is constructed through the net of polypropylene and surrounds it. These healing-in processes secure the implant against dislocation and protect the surrounding tissue from mechanical irritation or erosion, with firm and permanent suspension of the urinary bladder. The good tissue compatibility of the materials used is confirmed by wide clinical use.

[0020] The bursting pressures of the implant measured in vitro are far above the forces which occur physiologically under load in humans. The implant is extendable unidirectionally by about one third of its starting length.

[0021] The implant shown in Figure 1 has a base 1 of

triangle-like shape. Deviations from this are possible. As already mentioned, the first projections 5 and 6 also do not have to run in exactly the opposite direction to the second projections 7 and 8, respectively. The precise shape of the implant can be adapted to suit the anatomical circumstances of the patient.

[0022] The build-up of the layers described for the implant and the choice of material also serve only as an example. Other tissue-compatible materials can similarly be used.

[0023] One possibility of how the implant according to the invention can be inserted in a surgical operation is described in the following.

[0024] The spatium retropubicum is exposed by a Pfannenstiel's incision. After the apex of the bladder has been loosened from the peritoneum down to the vagina, the bladder is removed from the roof of the vagina proximally approximately a good two finger-widths up to the bladder neck and there only approximately one finger-width. The vessels running laterally and the ureter are to be protected carefully. This preparative procedure can be facilitated by preoperative injection under the vagina with saline solution alone or by addition of suprarenin 1:200,000. It is advisable to tampon the vagina. With an indwelling catheter, preparation is effected with an Overholt and scissors between the rear wall of the bladder and vagina distally and laterally, so that the Overholt tip can be seen on both sides paraurethrally in the spatium retropubicum.

[0025] From retrosymphyseally to both sides of the urethra/bladder neck angle, in each case a strong guide thread is drawn with the Overholt between the bladder and vagina. On these guide threads the two second projections 7, 8 or the front (proximal) bridles of the implant can be drawn retrosymphyseally between the vagina and bladder and positioned exactly. The wide base 1 of the implant comes to rest between the bladder and vagina. It should be ensured that the position of the alloplastic implant extends sufficiently far below the bladder neck in order to eliminate an existing insufficiency of the bladder neck or so that such an insufficiency cannot develop. The two first projections 5, 6 or rear (distal) retropubic bridles are passed by the urethra on both sides and fixed to the ligamentum pubicum superior behind the two pubic rami.

[0026] The rear wall of the bladder from the bladder neck to the apex of the bladder rests with a large surface area on the implant. When the implant is introduced, it is to be ensured that the often very thin wall of the bladder is not pushed towards the urethra, but is tightened abdominally. If the bladder tissue wrinkles in the region of the bladder neck, prolapse of this excess portion of the wall of the bladder may later result here.

[0027] Nevertheless, to avoid dislocation a sufficient number of fine monofilament fixation sutures (e.g. with thread thicknesses 4/0) is advisable. It is appropriate to pin the vagina to the implant on both sides with single-knot sutures and thus also to incorporate the vagina into

the suspension.

[0028] Before fixing the first projections 5, 6, the urinary bladder is filled with about 300 ml saline solution, to ensure that sufficient space remains for the urinary bladder to expand and to maintain an adequate bladder capacity. The two second projections 7, 8 of the implant are pulled right and left through the musculus rectus and apposed crosswise over this.

[0029] Pulling too tightly on the second projections 7, 8 carries the risk of severely limiting the retropubic space and therefore the possibility of expansion of the urinary bladder.

[0030] To avoid infection, opening of the bladder or suprapubic draining of urine should be refrained from as far as possible.

[0031] The use of the implant according to the invention is not to be interpreted as a universal method, but is, in particular, a reliable method in extreme situations of a descensus vesicae with generalized weakness and rarification of the tissue texture in the pelvic floor. Suspension of the urinary bladder with the implant is particularly suitable in the event of pronounced recurrences, including after several previous operations. In addition to rapid postoperative mobilization, rapid occupational integration is also ensured if the floor of the pelvis is exposed to high stress due to heavy lifting. In extremely obese patients with vertical and rotatory descensus, it would be conceivable to use the implant according to the invention as a primary intervention. The essential advantage lies in the wide-area, absolutely stable, bilateral fixation of the urinary bladder both in the bladder neck region and in the region of the apex of the bladder. The urinary bladder is supported elastically as on a hammock as a result of the implant, regardless of the condition of the pelvic floor. Renewed prolapse or descensus can reliably be avoided even under load. Since with the implant not only the bladder outlet but the entire urinary bladder is incorporated in a broad fixed support which supports the entire base of the bladder, by suspension of the implant it is not an increase in the discharge resistance which is aimed for but exclusively stress-proof relieving of the sphincter vesicae externus. There is no risk of obstruction if the implant is introduced correctly.

Claims

1. Implant for suspension of the urinary bladder in cases of incontinence of urine in women, having a flat, flexible basic structure in which two first projections (5, 6) and two second projections (7, 8) start from a triangle-like to elongated oval base (1), the two first projections (5, 6) running on opposite sides of the longitudinal axis (L-L) of the base (1) and the two second projections (7, 8) running generally in the opposite direction to the two first projections (5, 6) on opposite sides of the longitudinal axis (L-L) of

the base (1).

2. Implant according to Claim 1, characterized in that the basic structure is constructed symmetrically to the longitudinal axis (L-L) of the base (1).
3. Implant according to Claim 1 or 2, characterized in that the two first projections (5, 6) and the two second projections (7, 8) are bridle-like.
4. Implant according to one of the preceding claims, characterized in that the two first projections (5, 6) are shorter than the two second projections (7, 8).
5. Implant according to one of the preceding claims, characterized in that the base (1) is triangle-like and the two first projections (5, 6) start from the base (1) close to the corner (2) through which the longitudinal axis (L-L) of the base (1) runs, but at a distance therefrom, so that a semicircular to oval extension is constructed between the two first projections (5, 6) in the region of the corner (2) to support the bladder neck and the proximal urethra.
6. Implant according to Claim 5, characterized in that the two first projections (5, 6) run at a sharp angle, which is less than 20°, to the longitudinal axis (L-L) of the base (1), and in that the two second projections (7, 8), starting from the other two corners (3, 4) of the base (1), run essentially parallel to the longitudinal axis (L-L) of the base (1).
7. Implant according to one of the preceding claims, characterized in that the basic structure comprises a non-absorbable material.
8. Implant according to Claim 7, characterized in that the non-absorbable material is polypropylene.
9. Implant according to one of the preceding claims, characterized in that the basic structure comprises an absorbable material.
10. Implant according to Claim 9, characterized in that the absorbable material is a mixture of polyglactin 910 and polydioxanone.
11. Implant according to one of the preceding claims, characterized in that the basic structure has several layers.
12. Implant according to Claim 11, characterized in that the basic structure is built up in three layers, a net of polypropylene being provided with a porous coating of a composite material of polyglactin 910 and polydioxanone on both sides.

Patentansprüche

1. Implantat zur Suspension der Harnblase bei Harninkontinenz der Frau, mit einer flächigen, flexiblen Grundstruktur, bei der von einer dreieckähnlichen bis länglich ovalen Basis (1) zwei erste Fortsätze (5, 6) und zwei zweite Fortsätze (7, 8) ausgehen, wobei die beiden ersten Fortsätze (5, 6) auf gegenüberliegenden Seiten der Längsachse (L-L) der Basis (1) verlaufen und wobei die beiden zweiten Fortsätze (7, 8), generell entgegengesetzt zu den beiden ersten Fortsätzen (5, 6), auf gegenüberliegenden Seiten der Längsachse (L-L) der Basis (1) verlaufen.
2. Implantat nach Anspruch 1, **dadurch gekennzeichnet, daß** die Grundstruktur symmetrisch zur Längsachse (L-L) der Basis (1) ausgestaltet ist.
3. Implantat nach Anspruch 1 oder 2, **dadurch gekennzeichnet, daß** die beiden ersten Fortsätze (5, 6) und die beiden zweiten Fortsätze (7, 8) zügelartig sind.
4. Implantat nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** die beiden ersten Fortsätze (5, 6) kürzer sind als die beiden zweiten Fortsätze (7, 8).
5. Implantat nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** die Basis (1) dreieckähnlich ist und die beiden ersten Fortsätze (5, 6) in der Nähe der Ecke (2), durch die die Längsachse (L-L) der Basis (1) verläuft, aber beabstandet dazu, von der Basis (1) ausgehen, so daß zwischen den beiden ersten Fortsätzen (5, 6) im Bereich der Ecke (2) eine halbrunde bis ovale Ausziehung zur Abstützung des Blasenhalsses und der proximalen Urethra ausgebildet ist.
6. Implantat nach Anspruch 5, **dadurch gekennzeichnet, daß** die beiden ersten Fortsätze (5, 6) unter einem spitzen Winkel, der kleiner ist als 20°, zur Längsachse (L-L) der Basis (1) verlaufen und daß die beiden zweiten Fortsätze (7, 8), ausgehend von den beiden übrigen Ecken (3, 4) der Basis (1), im wesentlichen parallel zur Längsachse (L-L) der Basis (1) verlaufen.
7. Implantat nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** die Grundstruktur ein nicht resorbierbares Material aufweist.
8. Implantat nach Anspruch 7, **dadurch gekennzeichnet, daß** das nicht resorbierbare Material Polypropylen ist.
9. Implantat nach einem der vorhergehenden Ansprüche,

che, dadurch gekennzeichnet, daß die Grundstruktur ein resorbierbares Material aufweist.

10. Implantat nach Anspruch 9, **dadurch gekennzeichnet, daß** das resorbierbare Material ein Gemisch aus Polyglactin 910 und Polydioxanon ist.
11. Implantat nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, daß** die Grundstruktur mehrere Schichten aufweist.
12. Implantat nach Anspruch 11, **dadurch gekennzeichnet, daß** die Grundstruktur dreischichtig aufgebaut ist, wobei ein Netz aus Polypropylen auf beiden Seiten mit einer porösen Beschichtung aus einem Kompositmaterial aus Polyglactin 910 und Polydioxanon versehen ist.

Revendications

1. Implant pour la suspension de la vessie dans les cas d'incontinence urinaire chez la femme, ayant une structure de base plate et flexible dans laquelle deux premières saillies (5, 6) et deux secondes saillies (7, 8) commencent par une base en forme de triangle pour aboutir à une base ovale allongée (1), les deux premières saillies s'étendant sur les deux côtés opposés de l'axe longitudinal (L-L) de la base (1) et les deux secondes saillies (7, 8) s'étendant généralement dans le sens opposé aux deux premières saillies (5, 6) sur les côtés opposés de l'axe longitudinal (L-L) de la base (1).
2. Implant selon la revendication 1, **caractérisé en ce que** la structure de base est construite symétriquement à l'axe longitudinal (L-L) de la base (1).
3. Implant selon la revendication 1 ou la revendication 2, **caractérisé en ce que** les deux premières saillies (5, 6) et les deux secondes saillies (7, 8) sont en forme de brides.
4. Implant selon l'une des revendications précédentes, **caractérisé en ce que** les deux premières saillies (5, 6) sont plus courtes que les deux secondes saillies (7, 8).
5. Implant selon l'une des revendications précédentes, **caractérisé en ce que** la base (1) est en forme de triangle et les deux premières saillies (5, 6) commencent de la base (1) près du coin (2) à travers lequel l'axe longitudinal (L-L) de la base (1) s'étend, mais à une distance de celui-ci, de sorte qu'une extension semi-circulaire à ovale soit créée entre les deux premières saillies (5, 6) dans la région du coin (2) pour soutenir le col de la vessie et l'urètre proximal.

6. Implant selon la revendication 5, **caractérisé en ce que** les deux premières saillies (5, 6) s'étendent à un angle aigu, qui est inférieur à 20°, par rapport à l'axe longitudinal (L-L) de la base (1), **et en ce que** les deux secondes saillies (7, 8), partant des deux autres coins (3, 4) de la base (1), s'étendent essentiellement parallèlement à l'axe longitudinal (L-L) de la base (1). 5
7. Implant selon l'une des revendications précédentes, **caractérisé en ce que** la structure de base comprend un matériau non absorbable. 10
8. Implant selon la revendication 7, **caractérisé en ce que** le matériau non absorbable est du polypropylène. 15
9. Implant selon l'une des revendications précédentes, **caractérisé en ce que** la structure de base comprend un matériau absorbable. 20
10. Implant selon la revendication 9, **caractérisé en ce que** le matériau absorbable est un mélange de polylactine 910 et de polydioxanone. 25
11. Implant selon l'une des revendications précédentes, **caractérisé en ce que** la structure de base possède plusieurs couches. 30
12. Implant selon la revendication 11, **caractérisé en ce que** la structure de base est constituée de trois couches, un filet de polypropylène étant doté d'un revêtement poreux d'un matériau composite de polylactine 910 et de polydioxanone sur les deux côtés. 35

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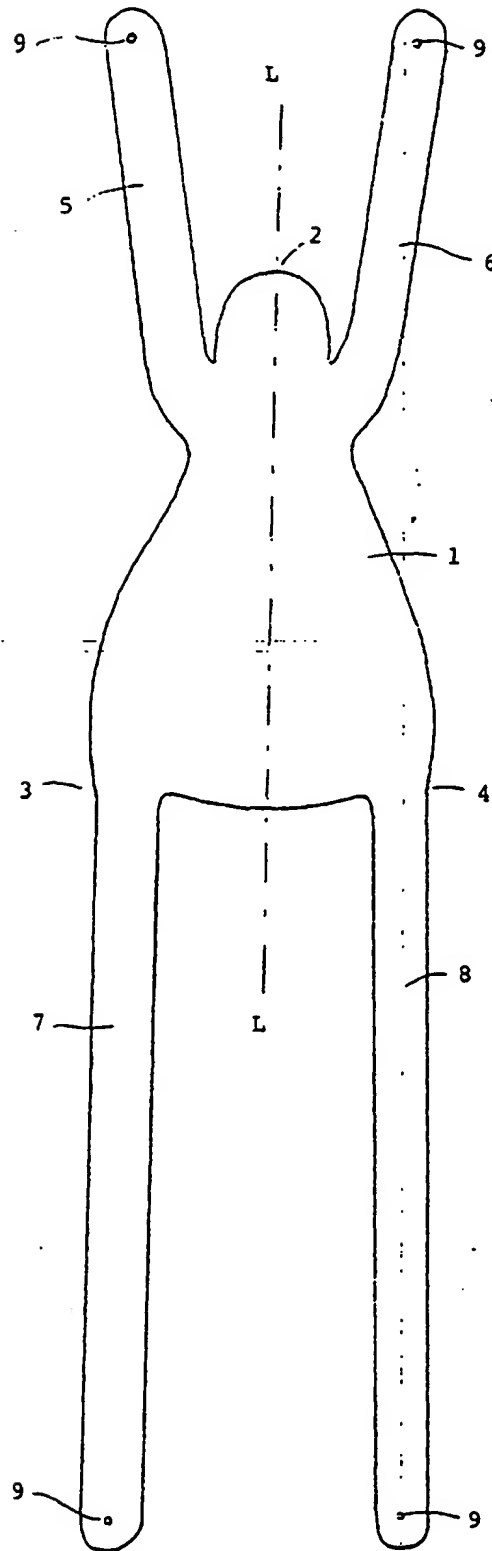


Fig. 1